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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,792	01/28/2004	Daniel C. Sigg	P-11213.00	3983

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EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 10/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/766,792	SIGG ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made of Applicant's Amendment, which was received by the Office on August 24, 2006. Claim 28 is new and has been added. Claims 1-28 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 3, 12, 14, 16-17 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner asserts that independent Claims 1, 22 and 28, wherein the catalytic layer is limited to converting nitrite/nitrate or nitrosothiols "found solely in the blood", are supported by Applicant's embodiment described at page 10, paragraph 34, lines 1-10 of Applicant's discloser and depicted in Applicant's Fig. 8A.

The Examiner is unable to find, however, throughout Applicant's disclosure, support for the further limitations presented in dependent Claims 3, 12, 14, 16-17 and 23. The Examiner makes reference to the embodiment described at page 10, paragraph 34, lines 10-20 of Applicant's disclosure and depicted in Applicant's Fig. 8B where it is specified that the catalytic layer *not only converts* nitrite/nitrate or nitrosothiols *found in the blood* but *also converts* nitrite/nitrate or nitrosothiols *present in a bulk matrix/reservoir* that can leak to the catalytic layer

in order to increase nitric oxide generation [emphasis added]. The Examiner is unable to find throughout Applicant's disclosure a description of an embodiment of the device where a catalytic layer converts nitrite/nitrate or nitrosothiols "found solely in the blood" further comprising a bulk matrix/reservoir/plug including lipophilic salts or nitrite/nitrate or nitrosothiols that can leak to the catalytic layer.

4. Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner is unable to find a description throughout Applicant's disclosure of "a plug" that includes "a layer of catalytic agent" where "the catalytic layer" converts nitrite/nitrate or nitrosothiols o*nly in the blood* to nitric oxide [emphasis added]. The Examiner makes specific reference to page 10, paragraph 34, lines 10-20 of Applicant's disclosure and the embodiment depicted in Applicant's Fig. 8B where it is described/shown that the catalytic layer *not only converts* nitrite/nitrate or nitrosothiols *found in the blood* but *also converts* nitrite/nitrate or nitrosothiols *present in a bulk matrix/reservoir* that can leak to the catalytic layer in order to increase nitric oxide generation [emphasis added].

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 3, 12, 14, 16-17 and 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the limitations presented in dependent

Claims 3, 12, 14, 16-17 and 23 are contradictory to the limitations presented in independent Claims 1 and 22. Claims 1 and 22 limit the catalytic agent to converting nitrite/nitrate or nitrosothiols found solely in the blood to nitric oxide, however, the dependent claims 3, 12, 14, 16-17 and 23 introduce a plug/reservoir/bulk matrix that contain nitrite/nitrate or nitrosothiols that can leak to the layer of catalytic agent. The Examiner suggests canceling Claims 3, 12, 14, 16-17 and 23 in order to overcome this rejection.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-4, 8-10, 12, 14 and 16-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stokes et al. (U.S. 5,282,844) (herein Stokes) in view of Batchelor et al. (U.S. 2002/0115559). As to Claims 1, 19-21 and 28, Stokes discloses an implantable medical electrical lead, read as an implantable therapy and/or diagnostic device (see Stokes Abstract and Fig. 1) comprising tines, read as fixation elements 26 adapted to secure the device to an implant site (see Stokes Figs. 2-3 and column 7, lines 4-8), one or more elongate conductors 28 extending within the elongated lead body 10 of the device (see Stokes Figs. 2 and 6 and column 8, lines 48-56) and a polymeric insulation tubing, read as a polymeric layer 12 overlaying a portion of the device in proximity to the implant site and inherently including an outer surface (see Stokes Figs. 1-2, 4, 6, 9 and 11, column 6, lines 49-52, column 7, lines 35-38 and column 8, lines 11-13). It is inherent that the one or more conductors 28 include electrically conductive

wires. Stokes discloses the claimed invention as discussed above except that the outer surface of the polymeric layer 12 is not disclosed to comprise a layer of a catalytic agent, having a nitrite reductase and/or nitrate reductase or nitrosothiol reductase activity such that the catalytic layer converts nitrite/nitrate or nitrosothiols found solely in the blood to nitric oxide.

Batchelor, however, teaches the use of biocompatible materials (i.e. polymers, metals, stainless steels, carbon and the like) provided with biocatalysts or biomimetic catalysts on their surface that have nitrite reductase, nitrate reductase and/or nitrosothiol reductase within such that the biocatalysts or biomimetic catalysts on the surface of such biocompatible materials can act on endogenous nitrite/nitrate or nitrosothiols within the blood creating a local increase in the nitric oxide levels at the surface of the material. Batchelor specifies that the biomimetic catalyst may comprise Cu(II) metal ion ligand complex. Batchelor specifies that coating these biocatalysts or biomimetic catalysts on the surface of biomedical materials, such as electrical leads, prevents platelet activation and adhesion onto these surfaces, thereby lowering thrombus formation and other complications associated with interactions between blood and foreign materials. Batchelor further teaches that coating these biocatalysts or biomimetic catalysts on the surface of biomedical materials is an improvement over NO-releasing materials well known in the art because they are relatively inexpensive to manufacture, have improved biocompatibility and are easier to store (see Batchelor Abstract, lines 3-12 and page 1-2, paragraphs 4-23). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the outer surface of the polymeric layer of Stokes to include a layer of biocatalysts or biomimetic catalysts as taught by Batchelor, since such a modification would provide an improved

antithrombogenic implantable therapy and/or diagnostic device which is inexpensive to manufacture and easy to store.

9. As to Claim 2, Stokes discloses that the polymeric layer 12 is formed of any flexible biocompatible and biostable insulator especially silicone rubber or polyurethane (see Stokes column 6, lines 49-52).

10. As to Claim 4, Stokes discloses that the device comprises an elongated lead body 10, which carries the one or more conductors 28 (see Stokes Fig. 1 and column 8, lines 48-56). In reference to Stokes Figs. 1 and 6, the Examiner takes the position that the polymeric layer 12 forms the device body 10 of the device (see Stokes Fig. 6) since the two are not depicted as separate elements (see Stokes Fig. 1).

11. As to Claim 8, the previously modified Stokes reference discloses the claimed invention as discussed above but does not expressly disclose an embodiment where the polymeric layer overlays the device body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device at taught by Stokes with a polymeric layer that overlays a device body, because Applicant has not disclosed that an overlaying polymeric layer provides an advantage, is used for a particular purpose, or solves a stated problem. One or ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a polymeric layer that forms the device body as taught by Stokes, because it provides a lead or device where the polymeric layer can not wear off or leave lost pieces of polymeric layer in a patient during use and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Stokes.

Therefore, it would have been obvious matters of design choice to further modify Stokes in view of Batchelor to obtain the invention as specified in the claim(s).

12. As to Claims 3 and 14, Batchelor discloses an alternate, preferred embodiment where an exogenous source, read as a bulk matrix of lipophilic salts or nitrite/nitrate or nitrosothiols are provided in the polymer matrix of the biocompatible material in order to create a reservoir of lipophilic salts or nitrite/nitrate or nitrosothiols that can continuously leak to the catalytic surface of the material (see Batchelor page 2, paragraphs 24-26).

13. As to Claims 12, Batchelor discloses an alternate, preferred embodiment where an exogenous source, read as a bulk matrix of lipophilic salts or nitrite/nitrate or nitrosothiols are provided in the polymer matrix of the biocompatible material in order to create a reservoir of lipophilic salts or nitrite/nitrate or nitrosothiols that can continuously leak to the catalytic surface of the material. It is inherent or at least obvious to one having ordinary skill in the art that in this embodiment of Batchelor the polymeric layer of the biomedical device having the layer of biocatalysts or biomimetic catalysts on its surface would include a plurality of pores extending there through otherwise the lipophilic salts or nitrite/nitrate or nitrosothiols would not be able to "continuously leak to the catalytic surface of the material" as specified by Batchelor (see Batchelor page 2, paragraphs 24-26).

14. As to Claim 16, Stokes discloses that it is well known in the art to utilize a polymeric plug held within the polymeric layer 12 of a device 10 which contains a liphophilic salt that can leak to the outside layer of the device in order to reach the device-tissue interface and prevent or reduce inflammation, irritability and subsequent excess fibrosis of tissue adjacent to the device/electrode itself (see Stokes column 3, lines 8-43).

15. As to Claim 17, Stokes discloses distal tip electrodes 22-22'''' coupled to the one or more conductors 28 and adapted to stimulate the implant site. Stokes further discloses that it is well known in the art to utilize a polymeric plug held within the polymeric layer 12 of a device 10 which contains a liphophilic salt that can leak to the outside layer of the device in order to reach the device-tissue interface and prevent or reduce inflammation, irritability and subsequent excess fibrosis of tissue adjacent to the device/electrode itself (see Stokes column 3, lines 8-43).

16. As to Claim 18, Stokes discloses that the polymeric plug may be formed of a material selected from the group consisting of silicone and polyurethane (see Stokes column 3, lines 8-43).

17. As to Claims 22 and 25-27, Stokes discloses an implantable medical electrical lead (see Stokes Fig. 1) comprising tines, read as distal fixation elements 26 adapted to secure the medical electrical lead to an implant site (see Stokes Figs. 2-3 and column 7, lines 4-8), one or more elongate conductors 28 (see Stokes Figs. 2 and 6 and column 8, lines 48-56), an electrode [22 (unipolar embodiment) or 22' (bipolar embodiment) or 22'' – 22'''' depicted in Stokes Figs. 8-11] coupled to a one of the one or more conductors 28, adapted to stimulate in proximity to the implant site and including an outer surface (see Stokes Figs. 2, 6 and 8-11 and column 7, lines 9-11, 26-30 and 41-49). Stokes discloses the claimed invention as discussed above except that the outer surfaces of the electrodes 22-22'''' are not disclosed to comprise a layer of a catalytic agent, having a nitrite reductase and/or nitrate reductase or nitrosothiol reductase activity where the catalytic layer converts nitrite/nitrate or nitrosothiols found only in the blood to nitric oxide.

Batchelor, however, teaches the use of biocompatible materials (i.e. polymers, metals, stainless steels, carbon and the like) provided with biocatalysts or biomimetic catalysts on their

surface that have nitrite reductase, nitrate reductase and/or nitrosothiol reductase within such that the biocatalysts or biomimetic catalysts on the surface of such biocompatible materials can act on endogenous nitrite/nitrate or nitrosothiols within the blood creating a local increase in the nitric oxide levels at the surface of the material. Batchelor specifies that the biomimetic catalyst may comprise Cu(II) metal ion ligand complex. Batchelor specifies that coating these biocatalysts or biomimetic catalysts on the surface of biomedical materials, such as biosensors, read as electrodes, prevents platelet activation and adhesion onto these surfaces, thereby lowering thrombus formation and other complications associated with interactions between blood and foreign materials. Batchelor further teaches that coating these biocatalysts or biomimetic catalysts on the surface of biomedical materials is an improvement over NO-releasing materials well known in the art because they are relatively inexpensive to manufacture, have improved biocompatibility and are easier to store (see Batchelor Abstract, lines 3-12 and page 1-2, paragraphs 4-23). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the outer surfaces of the electrodes of Stokes to include a layer of biocatalysts or biomimetic catalysts as taught by Batchelor, since such a modification would provide an improved antithrombogenic implantable therapy and/or diagnostic device which inexpensive to manufacture and easy to store.

18. As to Claim 23, Stokes discloses that the electrode 22 is a porous platinum ball electrode, inherently including a porous side wall and that it is well known in the art to utilize a polymeric plug held within the polymeric layer 12 of a device 10 which contains a liphophilic salt that can leak to the outside layer of the device in order to reach the device-tissue interface and prevent or

reduce inflammation, irritability and subsequent excess fibrosis of tissue adjacent to the device/electrode itself (see Stokes column 3, lines 8-43).

19. As to Claim 24, Stokes discloses that the polymeric plug may be formed of a material selected from the group consisting of silicone and polyurethane (see Stokes column 3, lines 8-43).

20. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stokes in view of Batchelor as applied to claim 1 above, and further in view of Halperin et al. (U.S. 5,564,434) (herein Halperin). The previously modified Stokes reference discloses the claimed invention as discussed above except that the device does not further comprise a physiological sensor capsule coupled to the one or more conductors where the outer surface of the polymeric layer overlays a portion of the sensor capsule.

Halperin, however, teaches that it is well known in the art to employ a metal housed physiological sensor module, read as a capsule 20 coupled to one or more extending conductors 14 and 16 in a pacemaker lead in order to enable rate responsive pacing functions employing temperature or pressure sensing (see Halperin Abstract, Figs. 2 and 3 and column 7, lines 19-67). Batchelor further specifies that the invention (the biocatalysts or biomimetic catalysts coating) may be applied to most medical devices with a biocompatible surface such as a polymer/metal catheter or biosensor (see Batchelor Abstract and page 2, paragraph 22). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Stokes in view of Batchelor and Halperin to include a physiological sensor capsule coupled to the one or more conductors where the outer surface of the polymeric layer overlays a portion of the sensor capsule in order to allow rate responsive pacing/defibrillation utilizing

parameters such as temperature and pressure and to provide the sensor capsule with improved biocompatibility, capabilities to prevent or inhibit platelet aggregation and/or to inhibit restonesis, capabilities to promote wound healing and/or to be able to be used as a vasodilator relaxing smooth muscles of a vessel prior to, during and/or after angioplasty or lead placement.

21. Claims 1-6, 8-10, 12, 14, 19-21 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borgersen et al. (U.S. 20010018607) (herein Borgersen) in view of Batchelor. As to Claims 1, 2, 4-5, 19-21 and 28, Borgersen discloses an implantable therapy delivery and/or diagnostic device 20 comprising a fixation element 48 adapted to secure the device 20 to an implant site, one or more elongate conductors extending within the device and an insulated body, read as a polymeric layer 40 fabricated of a plurality of co-extruded biocompatible elastomers (see Borgersen page 4, paragraph 35) such as polyurethane (see Borgersen page 6, paragraph 47) overlaying multiple lumens (see (Borgersen Figs. 2-3). Borgersen discloses the claimed invention as discussed above except that it is not specified that the polymeric layer 40 comprise a layer of a catalytic agent, having a nitrite reductase and/or nitrate reductase or nitrosothiol reductase activity such that the catalytic layer converts nitrite/nitrate or nitrosothiols found solely in the blood to nitric oxide.

Batchelor, however, teaches the use of biocompatible materials (i.e. polymers, metals, stainless steels, carbon and the like) provided with biocatalysts or biomimetic catalysts on their surface that have nitrite reductase, nitrate reductase and/or nitrosothiol reductase within such that the biocatalysts or biomimetic catalysts on the surface of such biocompatible materials can act on endogenous nitrite/nitrate or nitrosothiols within the blood creating a local increase in the nitric oxide levels at the surface of the material. Batchelor specifies that the biomimetic catalyst may

comprise Cu(II) metal ion ligand complex. Batchelor specifies that coating these biocatalysts or biomimetic catalysts on the surface of biomedical materials, such as electrical leads, prevents platelet activation and adhesion onto these surfaces, thereby lowering thrombus formation and other complications associated with interactions between blood and foreign materials. Batchelor further teaches that coating these biocatalysts or biomimetic catalysts on the surface of biomedical materials is an improvement over NO-releasing materials well known in the art because they are relatively inexpensive to manufacture, have improved biocompatibility and are easier to store (see Batchelor Abstract, lines 3-12 and page 1-2, paragraphs 4-23). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the outer surface of the polymeric layer of Borgersen to include a layer of biocatalysts or biomimetic catalysts as taught by Batchelor, since such a modification would provide an improved antithrombogenic implantable therapy and/or diagnostic device which is inexpensive to manufacture and easy to store.

22. As to Claims 8-9, the previously modified Borgersen reference discloses the claimed invention as discussed above but does not expressly disclose an embodiment where a polymeric layer overlays the device body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device at taught by Borgersen with a polymeric layer that overlays a device body, because Applicant has not disclosed that an overlaying polymeric layer provides an advantage, is used for a particular purpose, or solves a stated problem. One or ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a polymeric layer that forms the device body as taught by Borgersen, because it provides a lead or device where the polymeric layer can not wear off or

leave lost pieces of polymeric layer in a patient during use and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Borgersen.

Therefore, it would have been obvious matters of design choice to further modify Borgersen in view of Batchelor to obtain the invention as specified in the claim(s).

23. As to Claims 3 and 14, Batchelor discloses an alternate, preferred embodiment where an exogenous source, read as a bulk matrix of lipophilic salts or nitrite/nitrate or nitrosothiols are provided in the polymer matrix of the biocompatible material in order to create a reservoir of lipophilic salts or nitrite/nitrate or nitrosothiols that can continuously leak to the catalytic surface of the material (see Batchelor page 2, paragraphs 24-26).

24. As to Claims 6 and 10, in addition to the arguments previously presented Borgersen teaches that it is well known in the art for the body of such a device to comprise one or more insulated, conductive wires surrounded by an outer sheath (see Borgersen page 1, paragraph 3). Borgersen also teaches that electrode 42 may correspond to any conventionally available pace/sense and cardioversion/defibrillation electrodes (see Borgersen page 4, paragraph 36) and further discloses electrode 42 as a coil overlaying outer elastomer body, read as the outer surface of the polymeric layer 40 (see Borgersen Fig. 2).

25. As to Claims 12, Batchelor discloses an alternate, preferred embodiment where an exogenous source, read as a bulk matrix of lipophilic salts or nitrite/nitrate or nitrosothiols are provided in the polymer matrix of the biocompatible material in order to create a reservoir of lipophilic salts or nitrite/nitrate or nitrosothiols that can continuously leak to the catalytic surface of the material. It is inherent or at least obvious to one having ordinary skill in the art that in this embodiment of Batchelor the polymeric layer of the biomedical device having the layer of

biocatalysts or biomimetic catalysts on its surface would include a plurality of pores extending there through otherwise the lipophilic salts or nitrite/nitrate or nitrosothiols would not be able to "continuously leak to the catalytic surface of the material" as specified by Batchelor (see Batchelor page 2, paragraphs 24-26).

26. Claims 7, 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borgersen in view of Batchelor as applied to claims 1, 4 and 8 above, and further in view of Vachon (U.S. 5,861,023). The previously modified Borgerson reference discloses the claimed invention as discussed above except the coil electrode is not partially embedded in the outer surface of the polymeric layer.

Vachon, however, teaches that it is known to coat or cover a helically wound electrode with an electrically conductive polymeric material for inhibiting tissue ingrowth and for further reducing risk to the patient in the event removal of the device becomes necessary (see Vachon column 1, lines 54-61). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Borgersen in view of Batchelor and Vachon to comprise a coil electrode coupled to one of the one or more wire conductors and partially embedded in the outer surface of the polymeric layer forming the device body to improve the inventions conductive objectives, to inhibit tissue ingrowth, and to further reduce risk to the patient in the even removal of the device becomes necessary.

Response to Arguments

27. Applicant's arguments with respect to claims 1-27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

28. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

29. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

30. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jessica L. Reidel 10/19/06
Examiner
Art Unit 3766

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766